Remarks

Claims 1-14, 18-34 and 36 are pending in the present application, claims 15 and 17 having been canceled without prejudice or disclaimer.

Claims 4, 5 and 9 have been amended so as not to recite the term "about". Claim 19 has been amended so as to more distinctly claim and broadly capture certain embodiments of the present invention. Support for each of these amendments is found throughout the specification as filed.

The first sentence of the specification has been amended to accurately reflect the status of the parent application 08/993,529.

The title of the application has been amended to more clearly indicate the subject matter to which the pending claims are directed

Formal drawings, which comply with the requirements of 37 C.F.R. § 1.84, have been submitted herewith.

I. Rejections Under 35 U.S.C. § 101

The Examiner rejects claims 1-14, 18-34 and 36 under 35 U.S.C. § 101 because the claimed invention allegedly "is not supported by either a specific and substantial asserted utility or a well-established utility." In particular, the Examiner alleges that:

> The specification fails to provide sufficient objective evidence of any activity for encoded proteins, or to show that these proteins even exist ... [t]here is no specific disease or specific function that is suggested by this limited homology. There is therefore no specific, substantial, or credible utility that is well-known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding murine PSP.
> The specification does not indicate that the sequences are full-length open reading frames. No evidence that the sequences are in frame and that the protein is actually produced is presented.

See, Paper No. 8, pages 3-4. Applicants respectfully disagree and traverse this rejection.

A rejection under 35 U.S.C. § 101 is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the Applicants in the written description of the invention. *See* M.P.E.P. §§ 2107.01(II), (III) at 2100-[29-31] (Rev. 1, Feb. 2000). In addition, Applicants need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."). *See,* M.P.E.P. at 2100-29. Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. M.P.E.P. § 2107.01(II)(B) at 2100-[29-30].

Moreover, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. M.P.E.P. § 2107.01(II)(A) at 2100-[31-32]. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants' assertion of utility. *See id.*; *see also, In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

Contrary to the Examiner's comments, Applicants have set forth in the specification, a specific, substantial and credible utility which supports the claimed polynucleotides of the present invention. In the specification at page 33, lines 15-23,

Applicants teach that "the invention provides a diagnostic method useful during diagnosis of a digestive, nonimmune defense, endocrine or immune system disorder, including cancers of these systems, which involves measuring the expression level of the gene encoding the hPSP protein." Therefore, Applicants submit that the specification clearly and specifically asserts a use for the claimed invention, *i.e.*, the diagnosis of cancers of the digestive system. The asserted utility for the claimed polynucleotides of the present invention is supported by a post filing date reference to which the Examiner's attention is respectfully directed, and which is attached hereto as Exhibit A (Ashkenazi, A.J., *et al.*, International Publication Number WO 00/53755 (September 14, 2000)).

Ashkenazi et al. (Exhibit A) disclose a polynucleotide which encodes the hPSP polypeptide of the present invention and identify this polynucleotide as "PRO1025". *See*, Exhibit A at page 17 lines 16-19, and Figure 25. Ashkenazi et al. demonstrate that the polynucleotide identified as "PRO1025" was upregulated (at least 2-fold) in 8 primary colon tumors as well as primary lung tumors, but not in any cell line model analyzed. *See*, Exhibit A at page 182, lines 21-28; and pages 153-156, Table 5B. Given the specificity of upregulation of the polynucleotide identified as "PRO1025," Ashkenazi et al. determine "it is likely associated with tumor formation and/or growth." *See*, Exhibit A at page 182, lines 21-28. Because the polypeptide encoded by the polynucleotide identified by Ashkenazi et al. as "PRO1025" is identical to hPSP of the present invention, and because the polynucleotide identified by Ashkenazi et al. as "PRO1025" is specifically upregulated in colon cancer, the observations described above confirm Applicants' assertion of a specific utility that the hPSP polypeptides, antibodies and polynucleotides of the present invention will be useful in the diagnosis of colon cancer.

Thus, polynucleotides of the invention, together with polypeptides which they encode and antibodies specific for those polypeptides, may be used in the diagnosis of diseases of the digestive system including cancers such as colon cancer (*See*, e.g., Page 5, lines 28-32; Page 8, lines 27-30; Page 9, lines 22-28; and Page 32, line 20 through Page 37, line 12). Applicants submit that, for example, the use of polypeptides, antibodies, or polynucleotides of the invention, in the detection of colon cancer, is a specific utility in that detection of this disorder is not possible with all polypeptides. This utility is also substantial in that improved detection of this disorder would substantially benefit patients and their healthcare providers throughout the world.

In light of the above facts, Applicants submit that one of ordinary skill in the art would have found the Applicants' asserted utility to be more likely than not true, and therefore the Applicants asserted utility is credible. Therefore, Applicants argue that the present invention meets the statutory utility requirement under 35 U.S.C. § 101, and as further described in the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

Other than the conclusory statements that the invention lacks utility, the Examiner has presented no arguments as to why Applicants' asserted utility is not credible. In arguing that Applicants' asserted utility is not credible, the Examiner must attack (a) the logic underlying the assertion as seriously flawed or (b) the facts upon which the assertion is based as inconsistent with the logic underlying the assertion. *See*, Revised Interim Utility Guidelines Training Materials, p. 5. In the instant rejection, the Examiner has set forth no arguments as to why Applicants' logic (that human Parotid Secretory Protein polynucleotides may be used in the detection and/or diagnosis of colon cancer) is flawed or that the facts upon which the logic is based on, are inconsistent with the underlying

assertion. Thus, the Examiner has failed to make even a *prima facie* showing that Applicants' asserted utility is not credible.

Applicants submit that the asserted utilities for polynucleotides and sequences encoding human parotid secretory protein are specific and substantial ("the general rule [is] that the treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101." (Revised Interim Utility Guidelines Training Materials, p. 6)). In addition, Applicants submit that these utilities are credible. The Examiner has failed, however, to provide any countervailing statements as to why these particular utilities are not specific, substantial and credible.

Even assuming, *arguendo,* the Examiner has established a *prima facie* showing that the claimed invention lacks utility, Applicants respectfully submit that they have rebutted the Examiner's showing by proffering sufficient evidence to lead one skilled in the art to conclude that the asserted utilities are more likely than not true. Applicants have directed the Examiner to the specification where clear and specific assertions are made in support of patentable utilities of human Parotid Secretory Protein and sequences of the present invention.

In view of the above, Applicants submit that the asserted utilities of the invention meet the statutory requirement set forth in 35 U.S.C. § 101. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner also rejects claims 1-14, 18-34 and 36 under 35 U.S.C. § 112, first paragraph. Specifically, it is the Examiner's contention that claims 1-14, 18-34 and 36 are "not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth in the rejection under 35 USC § 101 above, one

skilled in the art clearly would not know how to use the claimed invention." *See*, Paper No. 8, Page 7.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, Applicants respectfully assert that the claimed invention is supported by a specific and substantial, credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. § 101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-28. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention.

II. Rejections Under 35 U.S.C. § 112, first paragraph

A. Enablement

The Examiner rejects claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, as allegedly containing "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *See*, Paper No. 8, pages 7-11.

Initially, Applicants respectfully direct the Examiner's attention to the attached Statement by Attorney for Applicants Regarding Permanence and Availability of Deposited Plasmids. The Statement satisfies the concerns raised by the Examiner and states that the hPSP cDNA has been deposited at an acceptable depositary and that the criteria set forth in 37 C.F.R. §§ 1.801-1.809 have been met. Accordingly, Applicants respectfully request that the instant rejection of the claims directed to the cDNA clone

contained in ATCC Deposit No. 97811, on grounds of inaccessibility of the claimed cDNA, should be reconsidered and withdrawn.

The Examiner has further rejected claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, for allegedly failing to provide "a sufficient enabling description of the claimed invention." More particularly, the Examiner alleges that:

> "[t]here does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make the various nucleic acids recited in the instant claims. A person of skill in the art would not know which sequences are essential and which sequences are non-essential ... *for the functional properties of the polypeptide.*

See, Paper No. 8, pages 9-10. The rejection is respectfully traversed.

Preliminarily, Applicants respectfully point out that the Examiner has failed to provide evidence or reasoning to support the present rejection of claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, for lack of enablement. The M.P.E.P. states that "[i]f the claim is rejected as broader than the enabling disclosure, the reason for so holding should be given." *See*, M.P.E.P. § 707.07(d). Furthermore, evidence and/or reasoning to support rejection of any of claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, for lack of enablement has not been proffered. Accordingly, Applicants respectfully request that rejection of these claims under 35 U.S.C. § 112, first paragraph, for lack of enablement be withdrawn.

It is well settled that the test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 8 U.S.P.Q. 2d 1217 (Fed. Cir. 1988). Under 35 U.S.C. § 112, an inventor is not required to disclose "a test of every species encompassed by their claims," even in an unpredictable art. *In re*

Angstadt, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976) (emphasis in original). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1376, 1384 (Fed. Cir. 1986). This is so even if the amount of experimentation required is laborious. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

Applicants assert that one reasonably skilled in the art, armed with the disclosure in the present specification coupled with information known in the art at the time the application was filed, could make and use the claimed polynucleotides, without undue experimentation. Therefore the claimed polynucleotides are fully enabled within the meaning of 35 U.S.C. §112.

Applicants' respectfully point out that it is not necessary for the claimed polynucleotides, or any polypeptides encoded thereby, to be "biologically active" or to be defined by "functional properties," in order for them to be fully enabled. Rather, the claimed polynucleotides need merely have application in a single use. The nucleic acids of the invention, in fact, have several uses asserted in the specification. These include use as an agent that hybridizes to other polynucleotides, (*e.g.*, a primer or a probe). One of skill in the art would be capable of routinely using a polynucleotide of the claimed invention for such a purpose. For example, one or more claimed polynucleotides may be used in the diagnosis of diseases of the digestive system and the non-immune defense of gastrointestinal mucosal surfaces. *See* e.g., specification at Page 5, lines 28-32; Page 8, lines 27-30; Page 9, lines 22-28; and Page 32, line 20 through Page 37, line 12. Use of the claimed nucleic acids as a nucleotide primer was routine and well within the abilities of those of ordinary skill in the relevant arts on the priority date of the present invention. *See e.g.*, specification at Page 43, lines 8-19; Page 44, lines 16-29; Page 47, line 25 to Page 48 line 2; and Page 31, line 13 through page 32, line 16. Accordingly, Applicants contend

that one of ordinary skill in the art would have been able to routinely use the nucleic acids commensurate with the scope of the claims.

Furthermore, under 35 U.S.C. § 112, an inventor is not required to disclose "a test of every species encompassed by their claims," even in an unpredictable art. *In re Angstadt*, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976) (emphasis in original). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1376, 1384 (Fed. Cir. 1986). This is so even if the amount of experimentation required is laborious. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Furthermore enablement is not precluded even if some embodiments of the claimed invention are inoperative. Indeed, the M.P.E.P. states that "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. *See*, M.P.E.P. § 2164.08(b).

Applicants assert that the Examiner has underestimated the level of skill of the skilled artisan and the teachings of the present specification. The skilled molecular biologist, enlightened by the teaching of the present specification, is more than capable of routinely determining whether a polynucleotide encompassed by the claims has uses commensurate in scope with the instant claims.

In view of the above remarks, Applicants believe the Examiner's concerns have been fully addressed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, for lack of enablement.

B. Written Description

The Examiner rejects claims 1-14, 18-20, 26-34 and 36, under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *See*, Paper No. 8, page 11. More specifically the Examiner states:

> [a]pplicant has disclosed specific nucleic acid of SEQ ID NOS:I and amino acid of SEQ ID NO:2 therefore, the skilled artisan cannot envision all the contemplated nucleic acid sequence possibilities recited in the instant claims.

See, Paper No. 8, page 12, lines 29-31.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art could reasonably conclude that Applicants had possession of the polynucleotides encompassed by the rejected claims, in the present application as filed. Furthermore, Applicants submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed,'" *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000). Further, the Federal Circuit has emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification; and not whether the specific

embodiments had been explicitly described or exemplified. Indeed, the court noted that "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000) (emphasis added).

It is well established that a "gene is a chemical compound, albeit a complex one". *Amgen, Inc. v. Chugai Pharamceutical Co., LTD.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Thus, the claims of the instant application, directed to particular polynucleotides of the disclosed nucleic acid sequence of SEQ ID NO:1, are essentially chemical claims involving generic chemical formulae. As stated by Judge Lourie in *University of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997), "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass." All of the objectives met by a generic chemical formula are similarly met by the explicit description in the instant specification of a polynucleotide sequence (*i.e.* SEQ ID NO:1) and the amino acid sequence encoded thereby (SEQ ID NO:2). Accordingly, one skilled in the art would reasonably conclude that Applicants had possession of the polynucleotides encompassed by the rejected claims upon reading the present application as filed, and would immediately recognize that the Applicants had "invented what is claimed" (*Vas-Cath*, 935 F.2d at 1563). Therefore, the specification contains an adequate written description of the claimed polynucleotides. Applicants have provided the skilled artisan with a "generic formula" in the form of the nucleic acid sequence of SEQ ID NO:1, which indicates "with specificity what the generic claims encompass." Armed with this information "one skilled in the art can distinguish such a formula from others and can identify many of the species

that the claims encompass." Moreover, Applicants submit that one skilled in the art would be able to "visualize and recognize" innumerable members of the genus given the disclosure of the reference sequence common to all members of the genus. Indeed, the Written Description guidelines state:

> if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence.

See, M.P.E.P. § 2163(II)(A)(3)(a)(ii) at 2100-165. Thus Applicants assert that the specification has satisfied the requirements for written description as set forth in *Eli Lilly & Co.* Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Examiner appears to allege that Applicants are not in possession of a single polynucleotide sequence at least 95% identical to: (a) a polynucleotide encoding the amino acid sequence of SEQ ID NO:2; (b) a polynucleotide encoding the amino acid sequence encoded by the cDNA contained in ATCC Deposit No. 97811; (c) the nucleic acid sequence of SEQ ID NO:1; (d) the nucleic acid sequence of the cDNA contained in ATCC Deposit No. 97811; or (e) a polynucleotide encoding any one of the listed N- or C-terminal deletions of the amino acid sequence of SEQ ID NO:2 or of the amino acid sequence encoded by the cDNA contained in ATCC Deposit No. 97811. It is noted that the Examiner, in silence, appears to acknowledge that Applicants are in possession of polynucleotide sequence 100% identical to each of the described embodiments. That point having been established, Applicants submit that the specification as filed contains abundant written description to support claims drawn to a polynucleotide at least 95% identical to each polynucleotide explicitly disclosed in the present application. Explicit

written support for polynucleotides sharing at least 95% identity may be found, for example, at Page 7, lines 1-23; at Page 18, line 1 to Page 20, line 16; and at Page 28, line 19 to Page 29, line 2. Furthermore, the specification provides detailed teachings on methods used to determine the sequence identity shared by two or more polynucleotides (*See* Page 18, line 20 to Page 19, line 10).

Further embodiments of the invention, rejected by the Examiner in the present action and fully described in the specification as filed, include: (a) epitope-bearing portions of hPSP, which are described, for example, at Page 31, lines 1-13; (b) recombinant vectors and host cells comprising a polynucleotide of the invention as well as methods for making them, which are described, for example, at Page 20, line 17 to Page 22, line 28; and at Page 43, line 34 to Page 54, line 19; (c) polynucleotides identical to or at least 95% identical to at least 30 contiguous nucleic acid residues of a polynucleotide of the invention which are described, for example, at Page 15, lines 9-31; (d) polynucleotides comprising SEQ ID NO:1, or a polynucleotide encoding a mature hPSP polypeptide, or a polynucleotide identical to the cDNA contained in ATCC Deposit No. 97811, or a polynucleotide encoding at least 30 contiguous amino acids of hPSP, or a polynucleotide complementary to any of the claimed nucleic acid sequences, which are described, for example, at Page 5, line 34 to Page 6, line 1; at Page 6, lines 6-9; at Page 7, lines 1-17; at Page 8, lines 15-24; at Page 12, line 20 to Page 14, line 2; and at Page 16, lines 3-18; (e) a polynucleotide of the invention further comprising a heterologous polynucleotide, which may or may not encode a heterologous polypeptide, which are described, for example, at Page 20, line 30 to Page 21, line 20; at Page 21, lines 26-28; at Page 32, lines 5-17; at Page 43, line 35 to Page 46, line 32; and at Page 49, line 26 to Page 54, line 19; and (f) a composition comprising a polynucleotide encoding SEQ ID NO:2, the amino acid

sequence encoded by the cDNA of ATCC Deposit No.97811, or at least 30 contiguous amino acid residues of SEQ ID NO:2, which are described, for example, at Page 5, line 34 to Page 6, line 1; at Page 6, lines 6-9; at Page 7, lines 1-17; at Page 8, lines 15-24; at Page 12, line 20 to Page 14, line 2; at Page 15, lines 9-31; at Page 16, lines 3-18; at at Page 20, line 17 to Page 22, line 28; at Page 32, lines 5-17; and at Page 43, line 34 to Page 54, line 19. Accordingly, one skilled in the art, enlightened by the teachings of the present application, could readily envision all of the various polynucleotide sequences that comprise the specified polynucleotides as rejected by the Examiner.

In regard to the Examiner's contention that "the skilled artisan cannot envision all the contemplated nucleic acid sequence possibilities" Applicants respectfully disagree. The present application describes the human parotid secretory protein (hPSP) and the polynucleotides which encode it as well as variants and derivatives thereof. Applicants contend that the disclosure of structural features which are common to every member of the genus ensures that one skilled in the art could readily envision the claimed polynucleotide sequences, and therefore the written description requirement of 35 U.S.C. § 112, first paragraph, has been met. For example, the skilled artisan could clearly envision each of the polynucleotides comprising at least 30 contiguous nucleotides of SEQ ID NO:1 as a progression, *i.e.*, polynucleotides comprising nucleotides 1-30, 2-31, 3-22, etc. The skilled artisan could certainly further envision sequentially adding contiguous nucleotides to either end of any of the described embodiments. Indeed, nothing more than what is described in the specification would be required for the skilled artisan to identify every single one of the polynucleotides and polynucleotide fragments containing at least 30 nucleotides of SEQ ID NO:1. Likewise, the skilled artisan could easily substitute any given nucleotide for any other given nucleotide, or add or delete nucleotides, such that

nothing more than what is described in the specification would be required to identify every single one of the polynucleotides comprising nucleotide sequences that are at least 95% identical to the nucleotide sequence of SEQ ID NO:1. Furthermore, the skilled artisan could easily substitute any given codon for any other given codon encoding the same amino acid residue, or add or delete codons, such that nothing more than what is described in the specification would be required to identify every single one of the polynucleotides encoding at least 30 and/or at least 50 amino acid residues of the amino acid sequence of SEQ ID NO:2. Thus, it would be readily apparent to the skilled artisan that the Applicants had "invented what is claimed" (*Vas-Cath*, 935 F.2d at 1563).

For all of the above reasons, Applicants respectfully assert that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. Moreover, the specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. Therefore, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

In light of these clarifications, Applicants respectfully request that the Examiner's rejection of claims 1-14, 18-20, 26-34 and 36, under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

III. Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1, 4, 5, 9-14, 18-19, 28-34 and 36 under 35 U.S.C. § 112, second paragraph as allegedly being "indefinite for failing to particularly point out

and distinctly claim the subject matter which applicant regards as the invention." *See*, Paper No. 8, page 13. Applicants respectfully disagree and traverse these rejections.

A. The Examiner rejects claims 1, 5 and 18 on the basis that the calculation 95% identity between sequences is unclear, and claim 19 on the basis that "default parameters" unclear. Applicants respectfully disagree and contend that one of ordinary skill in the art would readily understand the meaning of "95% identity" and that determination of % identity between two sequences is a matter of simple arithmetic calculation using a widely known and accepted formula:

$$\%\ \text{identity equals} \quad \frac{\text{No of residues identical in two sequences X 100}}{\text{Total no of residues in reference sequence.}}$$

Further details outlining the use of this formula in the analysis of sequence identities and the calculation of 95% sequence identity, is found in the specification as filed, for example, at Page 18, lines 20-34. Furthermore, Applicant respectfully point out that claim 19 has been amended and no longer recites "using the Bestfit algorithm and default parameters" thereby obviating its rejection.

In light of the above comments and amendment, Applicants respectfully suggest that the present rejections have been obviated and request that they be reconsidered and withdrawn.

B. The Examiner rejects claims 4, 5, and 9 on the basis that it is unclear what is meant by the term "about." Applicants respectfully point out that claims 4, 5 and 9 have been amended to no longer recite the term "about," thereby obviating the present rejection.

Accordingly, Applicants respectfully request that the present rejection be reconsidered and withdrawn.

C. The Examiner rejects claim 5 on the basis that it is unclear what is meant by the terms "n-231," "1-m" or "n-m." Applicants respectfully point out that the identities of n and m are clearly indicated in claim 5. Support for such definitions of n and m is found in the specification as originally filed, for example, at page 23, line 27 through page 24, line 32. Accordingly, in the context of claim 5 the terms "n-231," "1-m" and "n-m" would be readily interpreted by one of ordinary skill in the art to identify specific ranges of amino acids of SEQ ID NO:2.

In light of these comments and explanations, Applicants respectfully request that the present rejection be reconsidered and withdrawn.

D. The Examiner rejects claim 14 on the basis that it is unclear what is meant by the terms "recombinant method." Applicants respectfully suggest that the term "recombinant method" has a generally accepted meaning within the art, which may be thought of as approximately the same as "a method using recombinant techniques."

In light of these comments and explanations, Applicants respectfully request that the present rejection be reconsidered and withdrawn.

E. The Examiner rejects claim 19 on the basis that it is unclear what is meant by the terms "fragment from the group." Applicants respectfully point out that claim 19 has been amended so as to no longer recite the term "fragment of the group."

Accordingly, Applicants respectfully request that the present rejection be reconsidered and withdrawn.

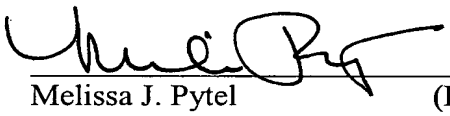
In light of the preceding comments, explanations and amendments, Applicants respectfully request that the Examiner's rejection of claims 1, 4, 5, 9-14, 18-19, 28-34 and 36 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the remarks of the present response be entered and made of record in the present application. The present application is believed to be in condition for allowance. Early notice to that effect is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted,

Dated: January 21, 2003



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MMW/MJP/BM

VIA HAND DELIVERY JANUARY 21st, 2003

Docket No.: PF348C1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Duan et al.

Application No.: 10/020,139 Group Art Unit: 1644

Filed: December 18, 2001 Examiner: M. Belyavskyi

For: Polynucleotides Encoding Human Parotid Secretory Protein (As Amended)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

The title on line 1 of page 1 with been replaced by the following rewritten title:

--Polynucleotides Encoding Human Parotid Secretory Protein--

The complete paragraph immediately after the title on page 1 has been replaced by the following rewritten paragraph:

--This application is a continuation of, and claims benefit under 35 U.S.C. § 120 of United States patent application Serial No. 08/993,529, filed December 18, 1997 and now abandoned, which is incorporated by reference in its entirety, which claims benefit under 35 U.S.C. § 119(e) based on U.S. Provisional Application No. 60/034,429, filed December 23, 1996, herein incorporated by reference in its entirety. --

In the Claims

Claims 15 and 17 have been canceled without prejudice or disclaimer.

Claims 4, 5, 9 and 19 have been replaced with the following rewritten claims:

--4. (Once Amended) The nucleic acid molecule of claim 1 wherein said polynucleotide has the nucleotide sequence in SEQ ID NO:1 encoding the mature form of the hPSP polypeptide having the amino acid sequence from ~~about~~ amino acid residue 1 to ~~about~~ amino acid residue 231 of SEQ ID NO:2.

5. (Once Amended) An isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95% identical to a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a polypeptide comprising the amino acid sequence at positions n-231 in SEQ ID NO:2, where n is an integer except zero in the range of -17 to +26.

(b) a nucleotide sequence encoding a polypeptide having the amino acid sequence of residues 1-m of SEQ ID NO:2, where m is an integer in the range of +220 to +231;

(c) a nucleotide sequence encoding a polypeptide having the amino acid sequence of residues n-m of SEQ ID NO:2, where n and m are integers as defined respectively in (a) and (b) above; and

(d) a nucleotide sequence encoding a polypeptide consisting of a portion of the complete hPSP amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97811 wherein said portion excludes from 1 to ~~about~~ 43 amino acids from the amino terminus of said complete amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97811;

(e) a nucleotide sequence encoding a polypeptide consisting of a portion of the complete hPSP amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97811 wherein said portion excludes or from 1 to ~~about~~ 11 amino acids from the carboxy terminus of said complete amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97811; and

(f) a nucleotide sequence encoding a polypeptide comprising a portion of the complete hPSP amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97811 wherein said portion include a combination of any of the amino terminal and carboxy terminal deletions in (d) and (e), above.

9. (Once Amended) An isolated nucleic acid molecule comprising a nucleic acid sequence which encodes an epitope-bearing portion of an hPSP polypeptide selected from the group consisting of: a polypeptide comprising amino acid residues from ~~about~~ Ser50 to ~~about~~ Leu66 of SEQ ID NO:2; a polypeptide comprising amino acid residues from ~~about~~ Glu97 to ~~about~~ Leu105 of SEQ ID NO:2; a polypeptide comprising amino acid residues from ~~about~~ Glu141 to ~~about~~ Gln148 of SEQ ID NO:2; and a polypeptide comprising amino acid residues from ~~about~~ Asp219 to ~~about~~ Leu227 of SEQ ID NO:2.

19. (Once Amended) An isolated polynucleotide comprising a nucleic acid sequence selected ~~fragment~~ from the group consisting of:

(a) a nucleic acid sequence encoding an amino acid sequence at least 95% identical~~, using the Bestfit algorithm and default parameters,~~ to a polypeptide of amino acids +1 to +231 of SEQ ID NO:2;

(b) a nucleic acid sequence encoding a polypeptide encoded by the human cDNA contained in ATCC Deposit No. 97811; and

(c) a nucleic acid sequence encoding a polypeptide of at least 30 contiguous amino acids of SEQ ID NO:2.--